

Listing of Claims:

The following listing reflects the claims currently pending in the application and replaces all prior versions and listings of claims in this application. No amendments are made herein.

1. (Previously presented) A low salt-containing aqueous composition comprising biologically active human IGF-I or a biologically active variant thereof in a concentration of about 250 mg/ml or greater and a pH of pH 5.0 or greater, wherein said variant is a polypeptide that has at least 80% amino acid sequence identity to the amino acid sequence of human IGF-I.

2. (Canceled)

3. (Previously presented) The composition of claim 1, wherein said human IGF-I or variant thereof is present in a concentration of about 250 mg/ml to about 500 mg/ml.

4. (Previously amended) The composition of claim 1, wherein said human IGF-I or variant thereof is present in a concentration of about 350 mg/ml, and wherein said composition has a density of about 1.07 g/ml and a viscosity of about 15,700 cps.

5-12. (Canceled)

13. (Previously presented) A kit for reconstituting a pharmaceutical composition comprising biologically active human IGF-I or biologically active variant thereof, said kit comprising the composition of claim 1 and separately a pharmaceutically acceptable buffered solution having a pH less than or equal to pH 5.0.

14-15. (Canceled)

16. (Previously presented) A pharmaceutical composition comprising the composition of claim 1, and a pharmaceutically acceptable carrier.

17. (Original) The pharmaceutical composition of claim 16, wherein said composition is a sustained-release formulation.

18. (Original) The pharmaceutical composition of claim 16, wherein said composition is a gel formulation.

19. (Previously presented) A cryogenically produced poly(D,L-lactide-co-glycolide) (PLGA) microsphere comprising the composition of claim 1.

20. (Previously presented) The microsphere of claim 19, wherein said microsphere comprises a lyophilized form of said composition.

21-27. (Canceled)

28. (Previously presented) The composition of claim 1, wherein said variant differs from the amino acid sequence for said human IGF-I by up to 5 amino acid residues.

29. (Previously presented) The composition of claim 1, wherein said variant differs from the amino acid sequence for said human IGF-I by up to 2 amino acid residues.

30. (Previously presented) The composition of claim 1, wherein said variant differs from the amino acid sequence for said human IGF-I by 1 amino acid residue.

31. (Previously presented) The composition of claim 1, wherein said human IGF-I is recombinant human IGF-I.

32. (Previously presented) The composition of claim 1, wherein said recombinant human IGF-I is present at a concentration of about 250 mg/ml to about 500 mg/ml.

33. (Previously presented) The composition of claim 1, wherein said recombinant human IGF-I is present at a concentration of about 350 mg/ml, and wherein said composition has a density of about 1.07 g/ml and a viscosity of about 15,700 cps.

34. (Previously presented) A low salt-containing aqueous composition comprising biologically active human IGF-I in a concentration of about 250 mg/ml or greater and a pH of pH 5.0 or greater.

35. (Previously presented) The composition of claim 34, wherein said human IGF-I is recombinant human IGF-I.

36. (Previously presented) The composition of claim 34, wherein said human IGF-I is present at a concentration of about 250 mg/ml to about 500 mg/ml.

37. (Previously presented) The composition of claim 34, wherein said human IGF-I is present at a concentration of about 350 mg/ml, and wherein said composition has a density of about 1.07 g/ml and a viscosity of about 15,700 cps.

38. (Previously presented) A pharmaceutical composition comprising the composition of claim 34, and a pharmaceutically acceptable carrier.

39. (Previously presented) A cryogenically produced poly(D,L-lactide-co-glycolide) (PLGA) microsphere comprising the composition of claim 34.

40. (Previously presented) A pharmaceutical composition comprising the composition of claim 37, and a pharmaceutically acceptable carrier.

41. (Previously presented) A cryogenically produced poly(D,L-lactide-co-glycolide) (PLGA) microsphere comprising the composition of claim 37.

42. (Previously presented) A low salt-containing aqueous composition comprising biologically active recombinant human IGF-I is a concentration of about 350 mg/ml, and wherein said composition has a density of about 1.07 g/ml and a viscosity of about 15,700 cps and a pH of pH 5.0 or greater.

43. (Previously presented) A pharmaceutical composition comprising the composition of claim 42, and a pharmaceutically acceptable carrier.

44. (Currently amended) A cryogenically produced poly(D,L-lactide-co-glycolide) (PLGA) microsphere comprising the composition of claim 42.

45. (Previously presented) A pharmaceutical composition comprising the composition of claim 1, and a pharmaceutically acceptable excipient.

46. (Previously presented) The pharmaceutical composition of claim 45, wherein said composition is a sustained-release formulation.

47. (Previously presented) The pharmaceutical composition of claim 45, wherein said composition is a gel formulation.

48. (Previously presented) A pharmaceutical composition comprising the composition of claim 34, and a pharmaceutically acceptable excipient.

49. (Previously presented) A pharmaceutical composition comprising the composition of claim 37, and a pharmaceutically acceptable excipient.

50. (Previously presented) A pharmaceutical composition comprising the composition of claim 42, and a pharmaceutically acceptable excipient.